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10/562,202	04/13/2006	Osamu Honmou	033873-0108	4131

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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
LONG, SCOTT	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,202	HONMOU ET AL.	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-9 and 11-28* is/are pending in the application.

4a) Of the above claim(s) *20-22, 25 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-9,11-19,23,24,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/9/08 and 1/28/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of Applicant's Remarks and Claim amendments, filed on 14 December 2008.

Claim Status

Claims 6-9 and 11-28 are pending. Claims 1-5 and 10 are cancelled. Claims 6-9 and 11 are amended. Claims 14-28 are newly submitted. However, claims 20-22, 25 and 28 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim (see Restriction section below). Claims 6-9, 11-19, 23-24, and 26-27 are under current examination.

Election/Restrictions

Newly submitted claims 20-22, 25, and 28 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 22 and 28 are species of the generic claim 9. In the previous action, an unclaimed species of the general method was rejected. In the previous action (pages 6-7), the examiner rejected claim 9 as anticipated by Twardzik (US2002/0123456) or Mahmood et al. (Neurosurgery Nov. 2001, 49(5):1196-1204) which used bone marrow derived mesenchymal stem cells for treating cranial nerve disease (including infarction). If the methods of previous claim 9 and newly presented claims 22 and 28 were initially

introduced together in an initial claim set, they would have been restricted as directed to distinct species, because the particular mesenchymal cells of claims 22 and 28 would required additional and burdensome searches to describe the cells derived from distinct methods and having particular markers. These two species of mesenchymal cells of the method of claim 9 would have been different from those recited in claim 1 (previously required by claim 9). Therefore, the examiner asserts that claims 22 and 28 are directed to distinct and restrictable species and are accordingly withdrawn.

Likewise, claims 20-21 and 25 are directed to methods distinct from the claims examined in the previous action, including a species of claim 23. While claim 23 was not previously rejected, the art used by the examiner describe delivering mesenchymal cells comprising transgenes to treat ischemia and infarction, while the new claim 25 is directed to methods of treating brain cancer. If claims 24 and 25 were initial filed claims, they would be species of the generic claim 23 and consequently restrictable. A search of a method for treating infarction would not necessarily overlap with a search for a method for treating brain tumors. Since the subject matter of a method of treating infarction has been essentially examined in the previous action, the examiner hereby withdraws claim 25 as drawn to a non-elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-22, 25 and 28 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 9 January 2008 and 28 January 2008 consisting of 2 sheets are compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

Priority

This application claims benefit as a 371 of PCT/JP04/09386 (filed 06/25/2004). The application also claims benefit from foreign application JAPAN 2003-185260 (filed 06/27/2003) and JAPAN 2003-432329 (filed 12/26/2003). The instant application has been granted the benefit date, 25 June 2004, from the application PCT/JP04/09386.

Response to Arguments - Claim Rejections 35 USC § 112

Response to Arguments – 35 USC 112, second paragraph

Claim amendments, filed 14 December 2007, with respect to claim 6 has been fully considered and are persuasive. The rejection of Claim 6 under 35 USC 112, second paragraph, has been made moot by the claim amendments submitted on 14 December 2008 and is hereby withdrawn.

Response to Arguments - Claim Rejections

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-5, 7-8 and 10 as anticipated over Mahmood et al. (Neurosurgery, Vol.49, No.5, November 2001: 1196-1204) is withdrawn in response to Applicant's amendment. However, claims 9 and 11-13 remain rejected as anticipated by Mahmood et al.

Applicant's arguments and claim amendments filed 14 December 2007 have been fully considered but they are not persuasive.

The applicant argues that the cells of Mahmood et al. are not the same as those used in the instant application. The applicant has submitted four references denoted as Exhibits 1-4 to support their position. The applicant suggests "the 'marrow stromal cells' described by Mahmood et al. and the 'mesenchymal stem cells' of the present invention are different cell populations" (Remarks, page 7). When the specification provides specific teachings, these supercede any teachings by the art. The examiner points out that claim 9 is not directed to "mesenchymal stem cells" but to “mesenchymal cells.” In addition, the specification states, “the term ‘mesenchymal cells’ preferably refers to, for example, bone marrow cells (mononuclear cell fraction of bone marrow cells; MCF

(mononuclear cell fraction)), cord blood cells, peripheral blood cells, mesenchymal stem cells (MSCs), or cells derived from these cells." (page 5, lines 30-32). The specification further indicates that "mesenchymal stem cells may differentiate…via stromal cells into nerves" (page 6, lines 6-8). Because the specification indicates that marrow stromal cells are derived from mesenchymal stem cells, the examiner believes the teachings of Mahmood et al. satisfy the limitation of "mesenchymal cells" as taught by the specification. Therefore, the examiner finds the applicant's arguments unpersuasive, regarding claims 9 and 11-13.

Accordingly, the applicant hereby maintains the rejection of claims 9 and 11-13 under 35 USC 102(b) as anticipated by Mahmood et al. (Neurosurgery, Vol.49, No.5, November 2001: 1196-1204) for the reasons of record and the comments above.

The rejection of claims 1-5 and 7-13 as anticipated over Twardzik et al. (US2002/0123465, published 5 September 2002) is withdrawn in response to Applicant's amendment or arguments.

The rejection of claims 1-5 as anticipated over Gold et al. (US2002/0168766, published 14 November 2002) is withdrawn in response to Applicant's amendment or arguments. However, claims 6-8 remain rejected as anticipated by Gold et al.

The applicant argues that "Gold et al., does not teach the genetically modified mesenchymal cells of claim 6 of the present application *per se*." (Remarks, page 8). Despite the applicant's assertion, Gold et al. anticipates instant claim 6 because all the limitations of this claim are taught by Gold et al. Gold et al. teach "mesenchymal cells differentiated from hES cells" (parag.0100). Gold et al. also teach methods of creating stable genetic alterations of cells (parag.0051). Gold et al. teach, "optionally, differentiated human PS cells suitable for conditioning medium can be further adapted—for example by genetically altering the cells to express a growth factor like bFGF, or to express TERT, or to immortalize the cells" (parag.0102). Gold et al. also teach, "Other reasons to genetically alter stem cells is to immortalize them by providing an expression system for the catalytic component of telomerase (TERT), or otherwise genetically adapt them for an in vitro use such as drug screening. For therapeutic applications, it may be beneficial to modify cells with therapeutic genes" (parag. 0146). MPEP 2131 teaches "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art." Brown v. 3M, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001). In the instant case, all the structures of the instant claims are taught by Gold et al. The applicant has not explained which features of claim 6 is not taught by Gold et al. Therefore, the examiner finds the applicant's arguments unpersuasive, regarding claims 6-8.

Accordingly, the applicant hereby maintains the rejection of claims 6-8 under 35 USC 102(b) as anticipated by Gold et al. (US2002/0168766) for the reasons of record and the comments above.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in

possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 USC § 112, p 1 "Written Description" Requirement;* (Federal Register/Vol 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Claim 17 is broadly drawn, such that it applies to any a genus of methods comprising administration of cranial nerve disease therapeutic agents to a patient at any one of the times selected from within 72 hours, within 24 hours, within 12 hours, within 6 hours and within 3 hours from the onset of a cerebral infarction. However, the specification teaches not "within" but "at" 3hr, 6hr, 12hr, 24hr, and 72hr (page 21, lines 23-24 and) or "after" 3hr, 12hr, 72hr (page 22, lines 3-4; page 23, lines 13-14).

Therefore, the examiner considers this limitation to be new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 11-15 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Mahmood et al (Neurosurgery, Vol.49, No.5, November 2001: 1196-1204).

Claim 9 is directed to a method for treating a cranial nerve disease comprising the in vivo administration to a patient of a therapeutically effective amount of a cranial nerve disease therapeutic agent for in vivo administration, comprising a mesenchymal cell as an active ingredient. Mahmood et al. teach, "transplantation studies in cerebral ischemia, functional outcome was significantly improved in MSC-transplanted rats compared with bone marrow-transplanted animals….Bone marrow or MSCs transplanted directly into the striatum and cortex of rat brain subjected to TBI or middle cerebral artery occlusion migrate…induce neurological and functional improvement… Intravenous transplantation has the advantage of carrying the cells over a much wider area." (page 1196, col.2). MSC is an acronym for marrow stromal cells. Mesenchymal progenitor cells are components of bone marrow stroma. Mahmood et al. specifically describe mesenchymal cells administered by IV methods (page 1200, col.2).

The specification states, "the term 'mesenchymal cells' preferably refers to, for example, bone marrow cells (mononuclear cell fraction of bone marrow cells; MCF (mononuclear cell fraction)), cord blood cells, peripheral blood cells, mesenchymal stem cells (MSCs), or cells derived from these cells." (page 5, lines 30-32). The specification further indicates that "mesenchymal stem cells may differentiate…via stromal cells into nerves" (page 6, lines 6-8). Because the specification indicates that marrow stromal cells are derived from mesenchymal stem cells, the examiner believes the teachings of

Mahmood et al. satisfy the limitation of "mesenchymal cells" as taught by the specification.

Claim 11 is directed to the method of claim 9 , wherein the cranial nerve disease is cerebral infarction. The examiner believes Mahmood's treatments of the cerebral artery occlusion satisfy this claim.

Claim 12 is directed to the method of claim 9, wherein the in vivo administration is intravenous administration. Mahmood et al. specifically describe mesenchymal cells administered by IV methods (page 1200, col.2).

Claim 13 is directed to the method of claim 9, wherein the mesenchymal cell is a bone marrow cell, a cord blood cell, or a peripheral blood cell. Mahmood et al. teach mesenchymal cells from bone marrow.

Claim 14 is directed to the method of claim 13, wherein the bone marrow cell is an autologous cell of the patient. Mahmood et al. teach autologous MSCs (page 1200, col.2).

Claim 15 is directed to the method of claim 11, wherein the severe cerebral infarction is in a hyper acute stage of an acute stage. The specification does not define acute or hyperacute stage cerebral infarction. Therefore, the examiner asserts that Mahmood's treatments the cerebral artery occlusion satisfy this limitation of claim 15.

Claim 17 is directed to the method of claim 11, wherein the cranial nerve disease therapeutic agent is administered to a patient at any one of the times selected from:...a) within 72 hours from the onset of a cerebral infarction of a several cerebral infarction.

Mahmood et al. teach administration of mesenchymal cells 24 hours after traumatic brain injury (abstract).

Claim 18 is directed to a method for neuroprotection of a cranial nerve disease patient comprising in vivo administration to a patient of a therapeutically effective amount of an agent comprising a mesenchymal cell as an active ingredient. The specification suggests that examples of cranial nerve diseases include "cerebral infarction, spinal cord injuries and demyelinating diseases" (page 4, lines 1-2). The examiner believes Mahmood's description of transplantation of mesenchymal cells into rat brains affected by cerebral artery occlusion satisfy this claim.

Claim 19 is directed to a method for regenerating the cranial nerve of a cranial nerve disease patient comprising the in vivo administration to a patient of a therapeutically effective amount of an agent comprising a mesenchymal cell as an active ingredient. Mahmood et al. teach "survival and growth of the graft within the brain" (page 1196, col.2).

Accordingly, Mahmood et al. anticipated the instant claims.

Claims 6-9, 11-13, 15-19, 23-24 and 26-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Kazuhiko et al (Molecular Therapy. Feb 2004. 9(2): 189-197).

Claim 6 is directed to a cranial nerve disease therapeutic agent for in vivo administration, comprising a mesenchymal cell as an active ingredient, wherein the mesenchymal cell is: (a) a mesenchymal cell that has been treated *ex vivo* with a

transfection vector comprising a BDNF gene, PLGF gene, GDNF gene, or IL-2 gene; or (b) an immortalized mesenchymal cell that has been treated *ex vivo* with a transfection vector comprising an hTERT gene. Kazuhiko et al. teach administration of "transfected…human MSC [mesenchymal stem cells] with the BDNF gene…contributed to improved functional recovery in a rat…MCAO model" (abstract).

Claim 7 is directed to the agent of claim 6, wherein the mesenchymal cell is a mesenchymal stem cell. Kazuhiko et al. use mesenchymal stem cells in their method.

Claim 8 is directed to the agent of claim 6, wherein the mesenchymal cell is a bone marrow cell, a cord blood cell, or a peripheral blood cell. Kazuhiko et al. teach their MSC are bone marrow stromal cells.

Claim 9 is directed to a method for treating a cranial nerve disease comprising the in vivo administration to a patient of a therapeutically effective amount of a cranial nerve disease therapeutic agent for in vivo administration, comprising a mesenchymal cell as an active ingredient. Kazuhiko et al. teach administration of "transfected…human MSC [mesenchymal stem cells] with the BDNF gene…contributed to improved functional recovery in a rat…MCAO model" (abstract).

Claim 11 is directed to the method of claim 9 , wherein the cranial nerve disease is cerebral infarction. Kazuhiko et al. teach a rat model of transient Middle Cerebral Artery Occlusion (abstract).

Claim 12 is directed to the method of claim 9, wherein the in vivo administration is intravenous administration. Kazuhiko et al. teach intravenous administration of MSC.

Claim 13 is directed to the method of claim 9, wherein the mesenchymal cell is a bone marrow cell, a cord blood cell, or a peripheral blood cell. Kazuhiko et al. teach mesenchymal cells from bone marrow.

Claim 15 is directed to the method of claim 11, wherein the severe cerebral infarction is in a hyper acute stage of an acute stage. The specification does not define acute or hyperacute stage cerebral infarction. Therefore, the examiner asserts that Kazuhiko's treatments the cerebral artery occlusion satisfy this limitation of claim 15.

Claim 16 is directed to the method of claim 9, wherein the mesenchymal cells is: (a) a mesenchymal cell that has been treated *ex vivo* with a transfection vector comprising a BDNF gene, PLGF gene, GDNF gene, or IL-2 gene; or (b) an immortalized mesenchymal cell that has been treated *ex vivo* with a transfection vector comprising an hTERT gene. Kazuhiko et al. teach administration of "transfected…human MSC [mesenchymal stem cells] with the BDNF gene…contributed to improved functional recovery in a rat…MCAO model" (abstract). The transfection of MSC was performed *in vitro* prior to transplantation (page 195, col.2, Adenovirus infection).

Claim 17 is directed to the method of claim 11, wherein the cranial nerve disease therapeutic agent is administered to a patient at any one of the times selected from:…a) within 72 hours from the onset of a cerebral infarction of a several cerebral infarction. Kazuhiko et al. teach administration of mesenchymal stem cells 24 hours after MCAO (page 196, col.1).

Claim 18 is directed to a method for neuroprotection of a cranial nerve disease patient comprising in vivo administration to a patient of a therapeutically effective

amount of an agent comprising a mesenchymal cell as an active ingredient. The specification suggests that examples of cranial nerve diseases include "cerebral infarction, spinal cord injuries and demyelinating diseases" (page 4, lines 1-2). The examiner believes Kazuhiko's description of transplantation of mesenchymal cells into rat brains affected by cerebral artery occlusion satisfy this claim.

Claim 19 is directed to a method for regenerating the cranial nerve of a cranial nerve disease patient comprising the in vivo administration to a patient of a therapeutically effective amount of an agent comprising a mesenchymal cell as an active ingredient. Kazuhiko et al. teach "functional recovery" of rats treated with MSC-BDNF, which also produced nerve growth factors and promotes "neuroprotective responses". (abstract and page 190, col.1).

Claim 23 is directed to a method for delivering therapeutic genes to a neurological disease site of a patient with neurological disease, comprising the in vivo administration of a therapeutically effective amount of mesenchymal cells to a patient in need thereof. Kazuhiko et al. teach administration of "transfected…human MSC [mesenchymal stem cells] with the BDNF gene…contributed to improved functional recovery in a rat…MCAO model" (abstract).

Claim 24 is directed to the method of claim 23, wherein the neurological disease is cerebral infarction. The model used by Kazuhiko et al. is a model of cerebral infarction.

Claim 26 is directed to the method of claim 24, wherein the in vivo administration is intravenous administration. Kazuhiko et al. teach IV administration (page 190, col.1).

Claim 27 is directed to the method of claim 25, wherein the in vivo administration is direct administration. Kazuhiko et al. teach intraparenchymal administration (page 190, col.1).

Accordingly, Kazuhiko et al. anticipated the instant claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SDL/ Scott Long
Patent Examiner, Art Unit 1633

/Janet L. Epps-Ford/
Primary Examiner, Art Unit 1633